

### Remarks/Arguments

Favorable consideration of this application is respectfully requested in view of the foregoing amendment and the following remarks.

Claims 1-2, 5-6 and 9-10 are pending. In response to the Restriction Requirement and the Examiner's withdrawal of Claim 3-4, 7-8 and 11-12 as being drawn to non-elected claims, Claims 3-4, 7-8 and 11-12 have been canceled without prejudice.

Claims 1-2, 5-6 and 9-10 have been rejected under 35 U.S.C. §102(b) as being anticipated by WO 98/41208 (Reed). Specifically, the Examiner states:

"The claims read on a method for opening potassium channels in the cell membranes of a mammal in need of such treatment comprising administering to the mammal an effective amount of a compound of the formula (in claims 1 and claim 2), namely unoprostone isopropyl, wherein said condition or disease state is hypertension, pulmonary hypertension, asthma, interstitial cystitis, urinary incontinence and other urogenital disorders, ischemic bowel disease, gastrointestinal motility disorders, arrhythmias, peripheral vascular disease, congestive heart failure, dysmenorrhea, angina or alopecia.

Reed teaches the ophthalmic administration of isopropyl unoprostone for the treatment of ocular hypertension, wherein said isopropyl unoprostone is administered within the dosage range of about 0.001 to about 0.30 weight percent (Examples 1-3). Examples 1-3, especially Table I, shows the efficacy of about 0.12% to about 0.18% isopropyl unoprostone in lowering intraocular pressure wherein about 30 microliters of the formulation were instilled into the eye of a rabbit.

Although Reed is silent about the activity of isopropyl unoprostone in opening potassium channels in the cell membranes of a mammal, such property or characteristics deems to be inherent to the prior art method of treating ocular hypertension. Especially in light of the instant disclosure (page 9, lines 7-12), the prior art administered dosage of isopropyl unoprostone in treating ocular hypertension lies well within the instantly claimed dosage range. Therefore, the prior art method directing the administration of isopropyl unoprostone inherently possessing a therapeutic effect for the same ultimate purpose as disclosed by Applicants anticipates Applicants' claims even absent explicit recitations of the mechanism of action."

Applicants respectfully traverse the rejection and submit that Reed does not anticipate Claims 1-2, 5-6 and 9-10 for the reasons stated below.

The present invention is directed to a method for opening potassium channels in the cell membranes of a mammal in need of such treatment comprising administering to the mammal an effective amount of a compound of the formula in Claims 1 and 2, and specifically isopropyl unoprostone recited in Claims 5 and 6. The specific conditions or disease states treated by the

presently claimed method as recited in Claims 9 and 10 are hypertension, pulmonary hypertension, asthma, interstitial cystitis, urinary incontinence and other urogenital disorders, ischemic bowel disease, gastrointestinal motility disorders, arrhythmias, peripheral vascular disease, congestive heart failure, dysmenorrhea, angina and alopecia. The specific condition, ocular hypertension, is not recited in Claims 9 and 10.

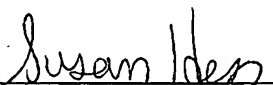
As acknowledged by the Examiner, Reed teaches ophthalmic administration of isopropyl unoprostone for the treatment of ocular hypertension and is completely silent about the activity of isopropyl unoprostone in opening potassium channels in the cell membranes of a mammal. Missing from Reed is any teaching of the administration of isopropyl unoprostone for treating hypertension, pulmonary hypertension or the other specific conditions or disease states recited in Claims 9 and 10. It is noted that ocular hypertension, i.e., increased pressure in the eye, is a completely different condition from hypertension, i.e., high blood pressure, pulmonary hypertension, i.e., high blood pressure in the pulmonary artery (the blood vessel that leads from the heart to the lungs) and the other conditions or disease states recited in Claims 9 and 10. Since Reed fails to teach treating hypertension, pulmonary hypertension or any other of the conditions or disease states recited in Claims 9 and 10 with isopropyl unoprostone, the activity of isopropyl unoprostone in opening potassium channels in the cell membranes of mammals cannot be deemed an inherent property of treating these specific conditions or disease states. Accordingly, Reed neither expressly nor inherently anticipates Claims 1-2, 5-6 and 9-10.

In view of the above, withdrawal of the rejection of Claims 1-2, 5-6 and 9-10 under 35 U.S.C. §102(b) is respectfully requested.

A good faith effort has been made to place the present application in condition for allowance. If the Examiner believes a telephone conference would be of value, he is requested to call the undersigned at the number listed below.

Respectfully submitted,

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 430  
East Hanover, NJ 07936-1080

  
\_\_\_\_\_  
Susan Hess  
Attorney for Applicants  
Reg. No. 37,350  
(862) 778-7859

Date: March 10, 2004